

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	Atty	. Docket: ARAI3
In re Application of: Norie ARAI et al.	)	Confirmation No.:
NOTIE ANAI Et al.	)	Art Unit:
Appln. No.: 10/765,905	)	Examiner:
Filed: January 29, 2004	)	Washington, D.C.
For: MUCOSAL IMMUNOREGULATORY AGENT AND ITS USE	) ) )	August 18, 2004

# INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office 2011 South Clark Place Customer Window, Mail Stop DD Crystal Plaza Two, Lobby, Room 1803 Arlington, Virginia 22202

#### Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

### (Check one of the boxes A-D)

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

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- [X] B. before the mailing date of a first Office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.
- 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., Form PTO/SB/08A) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate)

- [] A. Document(s) \_\_\_\_\_\_ is (are) U.S. patent(s) and/or published application(s). As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 U.S.C. §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (MPEP §609IIIA(2)(A)).
- [ ] B. Document(s) \_\_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_\_, and, in accordance with \$1.98(c), only a copy of each of the latter documents is enclosed.
- [ ] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 (or PTO/SB/08A) from the files of the prior application(s) or a fresh PTO-1449 (or PTO/SB/08A) listing these documents, and request that they be considered and made of record in accordance with \$1.98(d). Per

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37 CFR  $\S1.98(d)$ , copies of these documents need not be filed in this application.

- 3. Document(s) AC-AF and AI-AK is (are) not in the English language. In accordance with \$1.98(c), Applicant(s) states:
  - [ ] An English translation of each document \_\_\_\_\_ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
  - [X] A concise explanation of the relevance of document(s) AC-AF are found in the attached International search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
  - [ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

(insert concise explanation of relevance)

- [X] A concise explanation of the relevance of document(s) AI-AK can be found on page(s) 5 and 6 of the specification.
- [ ] A concise explanation of document(s) \_\_\_\_\_\_
  can be found on the attached sheet.
- 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- 5. Other information being provided for the examiner's consideration follows:

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# (insert other information)

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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PTO/SB/08a (08-03)

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Sui	bstitute fo	for form 1449A/PTO	U.S.		Complete if Known		
					Application Number	10/765,905	
11	<b>VFO</b>	RMATION [	DISCL	OSURE	Filing Date	29 January 2004	
S	TAT	EMENT BY	' APPL	PLICANT First Named Inventor		Norie ARAI et al	
		Group Art Unit	1623				
(use as many sheets as necessary)		Examiner Name					
	Sheet	1	of		Attorney Docket Number	ARAI=3A	

	FOREIGN PATENT DOCUMENTS						
		Foreign Patent Number	Dublication Date	Name of Detector of Assistant	Pages, Columns, Lines,		
Examiner Initials*	Cite No.1	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵	
	AC	JP 6-256219 A	9-13-1994				
	AD	JP 2000-07570 A	1-11-2000				
	AE	JP 2000-72579 A	3-7-2000				
	AF	JP 2000-93122 A	4-4-2000				
				<u> </u>			

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>			
	AG	AZUMA, and Yamamura, "Immunoadjuvants For Vaccine". Adv. Immunopharmacology. (1989), Vol. 4, pp. 149-158.				
	АН	GUILLEMARD, et al, "Simultaneous Production Of IFN-γ, IFN-α/β And Nitric Oxide In Peritoneal Macrophages From TDM-Treated Mice" Journal of Biological Regulators and Homeostatic Agents. (1998), Vol. 12, No. 4, pp. 106-111				
	Al	HASHIGUCHI, et al, "Cytokine secreted by Peyer's patch T cells and IgA production in intestine" Clinical Immunology (Rinsho-Meneki). (1998). Vol. 30, No. 11, pp. 1524-1531.				
	AJ	KIYONO, Clinical Immunology "IgA isotype regulation by mucosal T cells and epithelial cells" (Rinsho-Meneki). (1998), Vol. 30, No. 1, pp. 14-19.				
	AK	TAKAHASHI, Medical Immunology. "Mechanism for Mucosal Immunity to cholera" (1998), Vol. 27, No. 5-6, pp. 431-437.				

Examiner Signature	Date Considered	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.